RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE
GROUP 1615
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q64175
Kenichiro SHIROYAMA, et al.	
Appln. No.: 09/848,225	Group Art Unit: 1615
Confirmation No.: 6389	Examiner: CHANNAVAJJALA, Lakshmi Sarada
Filed: May 4, 2001	

For: CLEAR AQUEOUS CERAMIDE COMPOSITION

RESPONSE UNDER 37 C.F.R. § 1.116

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please consider the following Applicants' response to the outstanding rejection of July 3, 2006, twice extended to December 3, 2006, by an appropriate two-month petition for extension of time and fee submitted herewith.

RESPONSE

Review and reconsideration on the merits are requested.

At the time of rejection, claims 7 and 12-20 were pending. All of these claims are rejected over prior art.

Request for Telephone Interview

Applicants respectfully request a telephone interview concerning this application. The Examiner is requested to telephone the undersigned; if the Examiner does not telephone, the undersigned will contact the Examiner in about one week to 10 days.

THE PRIOR ART

U.S. 5,294,444 Nakamura et al (Nakamura); U.S. 5,641,495 Jokura et al (Jokura); U.S. 6,355,232 Kaneko et al (Kaneko).

The Rejections

Claims 7 and 12-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nakamura in view of Jokura.

Claims 7 and 12-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nakamura in view of Kaneko.

The Examiner's position on both rejections is set forth in the art in detail and will not be repeated here except as necessary to an understanding of Applicants' traversal, which is now presented.

Applicants later discuss the criticisms of the DECLARATION UNDER 37 C.F.R. §1.132 (the Declaration).

Request for Withdrawal of Finality

The Examiner is respectfully requested to reconsider the finality of the Action of July 3, 2006.

Although the Examiner characterizes the rejection as "new rejection", with respect to claim 7 and 12-20, these were rejected as being unpatentable over Nakamura in view of Kaneko.

However, Nakamura and the WO equivalent of Kaneko (WO 98/27958) were the exact same references the Examiner relied upon in the action of November 19, 2003.

Applicant's respectfully submit that in this situation, the rejection should not have been made final since the Examiner has essentially rejuvenated an old rejection, which Applicant's believed they had completely avoided in the past.

Under these circumstances, Applicant's request that the Examiner withdraw the finality of the Action of July 3, 2006, and notify the undersigned so that claim amendments, as appropriate, can freely be made.

Rejection over Nakamura in view of Jokura

Turning first to paragraph 3 of the Action, second full paragraph, the Examiner states:

"In particular, formula 2 of Jokura meets the description of ceramides formula of Nakamura."

More correctly, the materials of formula (2) of Jokura correspond to the amphiphatic lipids of formula (I) of Nakamura. The amphiphatic lipids of formula (I) of Nakamura are **not** ceramides.

Applicant's next address the issue as to whether Jokura discloses ceramides included in the natural ceramides of claim 15 of the present application or not. Referring to formula (1) of Jokura, it is seen that there must be a double bond adjacent to R_2 in formula (I) of Jokura. In distinction, the natural ceramide of claim 15 of the present application does not have such a

double bond in it's structural formula. Specifically, the compounds described in claim 15 are natural ceramides which are not described in Jokura.

Thirdly, the Examiner alleges that Jokura teaches ceramides and pseudoceramides are equivalent in their excellent skin moisturizing effects as well as low skin irritation. See the paragraph at the bottom of page 3 of the Action, first full sentence. This, however, is because the skin cosmetic composition containing component (A) of Jokura, which is a ceramide of formula (1 or a psuedoceramide of formula (2), component (B) which is a dicarboxylic acid and component (C) which is a salt of a dicarboxylic acid is excellent in skin moisturizing effects and gives low skin irritation, i.e., it is the combination of components (A), (B) and (C) which exhibits such effects of skin moisturizing and low skin irritation. Thus, the effects of skin moisturizing and low skin irritation do not arise from the sole use of component (A) which is a ceramide of formula (1) or a psuedoceramide of formula (2). Since Jokura describes the ceramide of formula (1) or the pseudoceramide of formula (2) at separate portions and as separate compounds, it is quite reasonable to assume or believe that this means that these components differ from each other. In fact, reference to Jokura at col. 2, shows that this is the case.

The Examiner's attention is also directed to the fact that in Nakamura, only the term "ceramide" is given, and there is no disclosure in Nakamura regarding specific compounds.

Considering the above, if Nakamura were to be combined with Jokura, the ceramide would be the ceramide of formula (1) of Jokura. However, as explained above, the ceramide of formula (1) of Jokura and the natural ceramide of claim 15 of the present application are different compounds.

Accordingly, Applicants respectfully submit that since neither Nakamura nor Jokura disclose or suggest the natural ceramide of claim 15 of the present application, any rejection based only these two references alone must fail.

Rejection over Nakamura in view of Kaneko

Applicants respectfully submit that "consisting essentially of" excludes the ionic surfactant of Nakamura. Even if addition of an ionic surfactant would not change the clear aqueous nature of the composition of the present invention, quite clearly such would not beneficially effect the composition of the present invention. See in this regard, Table 3, Application Example 1, where the addition of sodium POE(4) lauryl ether phosphate provides no beneficial effects to the present invention with respect to the clear aqueous nature thereof. However, as described in the present specification, ionic surfactants can lead to the danger of skin irritation (specification, page 3, lines 17-19), a factor which quite clearly would be viewed as undesirable by one of ordinary skill in the art. Therefore, as a result of the skin irritation associated with ionic surfactants, one skilled in the art would consider ionic surfactants to materially affect the claimed composition.

Applicants respectfully submit that even if one of ordinary skill in the art would be led to combine Nakamura and Kaneko, one of ordinary skill in the art would not be led to the present invention. Specifically, Nakamura is directed to a combination of 1) an amphipathic lipid, 2) a non-ionic surfactant, 3) an ionic surfactant, and 4) an aqueous medium. Aqueous medium 4) substantially includes polyhydric alcohols (e.g., glycerol and ethanol) and alcohols.

In distinction, the present invention relates to a combination of 1) a specific ceramide, 2) a long-chain fatty acid, 3) a nonionic surface active agent, and 4) water. Water 4) is water itself which does not include other components.

As is clear from Example 1 in the present specification, the present invention achieves aqueous clear (transparent) state characteristics by the combination of these four components. Comparing the present invention to Nakamura, Nakamura is different from the present invention in that ionic surfactants and polyhydric alcohols or alcohols are essential. In the present invention, ionic surfactants are not essential (rather, the use of ionic surfactants may result in skin irritation as described above), and polyhydric alcohols or alcohols are not essential. Accordingly, the present invention has superiority in that costs and load on the environment can be reduced.

In the Examples of Nakamura, it is disclosed that the products obtained are all transparent or semitransparent liquids. From this language, it is not clear whether the products were transparent or semitransparent. It could be concluded that a semitransparent product was obtained but it cannot be concluded with certainty that a transparent product was obtained. In the Examples of the present specification, all products are transparent (◎, except Example 2 wherein ceramide was added in an amount of 3% and that product was almost transparent (○). It is thus quite clear that using the combination of the present invention, the desired result of obtaining a clear aqueous ceramide composition is achieved. It is problematic whether such desired result is achieved in Nakamura.

Since Applicants traverse with respect to Nakamura, Applicants respectfully submit that even if the ceramide of Kaneko were to be used in the compositions of Nakamura, the present invention would not be rendered obvious.

Withdrawal of the rejections over Nakamura in view of Jokura and Nakamura in view of Kaneko is requested.

Criticism of the Declaration

First Criticism

Control samples, where the compositions have been prepared outside the claimed temperature conditions have not been tested. Therefore, in the absence of appropriate controls, the results presented do not establish the criticality of the temperature claimed.

Applicants respectfully submit the Examiner to be in error on this point.

The whole purpose of the testing which led to the results in TABLE 1 and the results in TABLE 2 was to show that the results with compositions of Examples 1-5 have excellent stability over a broad temperature range, whereas the compositions of the Comparative Examples are less stable, failing to achieve satisfactory results.

The testing was not to establish the "criticality" of temperature, rather, the testing was to show that at the same conditions the results obtained in accordance with the present invention are unexpected with respect to stability as compared to the Comparative Examples.

Second Criticism

However, example 1 and comparative example 2 differ in their components, not just for ceramides, but also in the presence or absence of sodium POE(4) laurylether phosphate, butylene glycol, cholesterol and the amounts of isostearic acid, POE (60) hydrogenated castor oil.

Again, the purpose of the experimentation was to establish the following.

In Comparative Example 2, no ceramide was present. Comparative Example 2 was presented to show that transparency cannot be obtained in the case that the system does not contain component (A) but contains components (B), (C) and (D). The Comparative Example was presented to show that transparency can be obtained only when the ratios of components (A), (B), (C) and (D) are in a specific range.

It is believe that Comparative Example 2 establishes this is the case and, by necessity, materials must somewhat differ between the comparisons.

Third Criticism

However, a careful review of the components of the compositions reveal that the pH of the composition is a result of the components added and has not been adjusted to a desired pH after adding the components.

"[A]pplicants have not shown any correlation between the optical clarity, presence of ceramides, pH and absence of skin irritations.

Optical clarity and the claimed ceramides (presence of the claimed ceramides) are correlated and pH in skin irritation are correlated. It is not clear that there is any correlation between optical clarity and skin irritation, and it is not clear that there is any correlation between the ceramides and the absence of skin irritation.

Applicants respectfully request the telephone interview to emphasize a discussion of the Declaration results.

Allowance is requested.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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